

REMARKS

With this amendment, claims 1, 4, 6, and 15-18 have been amended to further clarify the claimed subject matters. Claims 2, 3, 5, 7, 13 and 14 have been canceled without prejudice. In addition, new claim 19 has been added. Supports for the new claim can be found from, for example, paragraph [0047] of the published application. No new matter has been added. Claim 1, 4, 6, 8-12, and 15-19 remain pending.

Priority

The Examiner has required provision of a certified translation of Applicants' priority document in order to obtain the benefit of foreign priority.

It is respectfully submitted that an English translation of a priority document is not necessary to claim priority, but only to overcome an intervening reference (see M.P.E.P. 201.15). As no intervening reference has been cited, it is not necessary for Applicants to provide an English translation of a priority document.

Applicants assert that the priority claim has been properly made by listing of the priority document on the Declaration/Power of Attorney document which was filed with the application and by submission of a certified copy of the foreign application (see M.P.E.P. 201.14(b)). As this application is the US National phase under 35 U.S.C. § 371, a copy of the certified priority document is conveyed by the International Bureau (PCT Rule 17.2(a)).

Rejections under 35 U.S.C. § 112

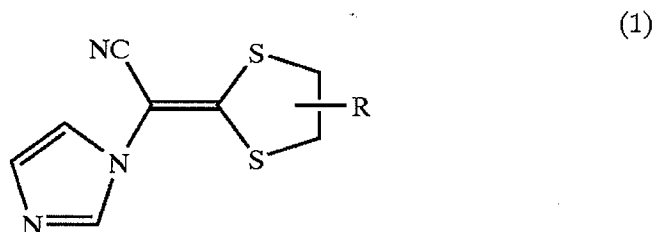
Claims 14 and 16 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. In reply, claim 16 has been rewritten to satisfy 35 U.S.C. 112. Applicants respectively request reconsideration of claim 16. Claim 14 is canceled without prejudice; therefore the rejection to claim 14 is now moot.

Rejections under 35 U.S.C. § 103

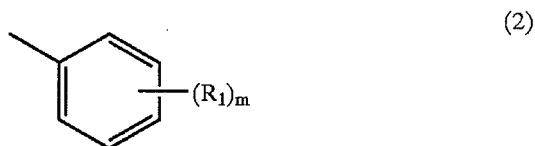
Claims 1-13, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over an International Patent Application Publication No. WO97/02821 to Kodama et al.

("Kodama), a Japanese Patent No. 7277975 ("JP 7277975"), and a U.S. Patent No. 6,403,063 to Sawyer ("Sawyer"). Applicants respectively traverse these rejections.

The independent claim 1 recites, among other things, an antifungal medicinal composition, comprising: (1) a film-forming agent; (2) a water-soluble plasticizer in a form of a solid or a paste at 20°C at 1 atm; and (3) an antifungal compound represented by a general formula (1) and/or a physiologically acceptable salt thereof, wherein the film-forming agent is one or two or more selected from the group consisting of ethyl cellulose, hydroxypropyl methylcellulose phthalate, and an acrylic resin emulsion; and the water-soluble plasticizer is a polymer or a copolymer of oxyethylene and/or oxypropylene having 70 or more of polymerization degree,



wherein, R represents an alkyl group having 1 to 8 carbon atoms, a cycloalkyl group having 3 to 6 carbon atoms, a methylene group, a lower alkenyl group, a halogen atom, a lower alkyl group substituted with a lower alkoxy group or a lower alkylthio group, or a group represented by a general formula (2) below



wherein, R₁ represents a hydrogen atom, a halogen atom, a linear- or branched-chain lower alkyl group, a lower alkoxy group, a haloalkoxy group, or a methylenedioxy group, and m represents an integral number of 1 to 3; wherein, the antifungal medicinal composition forms a coating film when applied to an application target, the coating film being in a viscous glass state.

As to claim 18, it recites, among other things, a method of producing an antifungal medicinal composition having (1) one or two or more selected from the group consisting of ethyl cellulose, hydroxypropyl methylcellulose phthalate, and an acrylic resin emulsion, (2) a polymer or copolymer of oxyethylene and/or oxypropylene, wherein the polymer or copolymer is water-

soluble, and (3) an antifungal compound represented by a general formula (1) and/or a physiologically acceptable salt thereof, comprising: dissolving alkyl sulfate which may have a polyoxyethylene group and/or alkyl phosphate which may have a polyoxyethylene group and the polymer or copolymer of oxyethylene and/or oxypropylene in a solvent containing acetone or methyl ethyl ketone; adding and dissolving in the solution the one or two or more selected from the group consisting of ethyl cellulose, hydroxypropyl methylcellulose phthalate, and an acrylic resin emulsion; and adding and dissolving in the solution the antifungal compound represented by the general formula (1) and/or the physiologically acceptable salt thereof; wherein, R represents an alkyl group having 1 to 8 carbon atoms, a cycloalkyl group having 3 to 6 carbon atoms, a methylene group, a lower alkenyl group, a halogen atom, a lower alkyl group substituted with a lower alkoxy group or a lower alkylthio group, or a group represented by a general formula (2); wherein, R1 represents a hydrogen atom, a halogen atom, a linear- or branched-chain lower alkyl group, a lower alkoxy group, a haloalkoxy group, or a methylenedioxy group, and m represents an integral number of 1 to 3; wherein, the antifungal medicinal composition is configured to form a coating film when applied to an application target, the coating film being in a viscous glass state.

The cited references, JP7277975, Kodama, and Sawyer, are related to an antifungal agent. In the office action, the Examiner asserted that Kodama teaches the antifungal agent as cited in claims 1 and 18. With this, the Examiner contended that the substitution of the antifungal agent of Kodama with the antifungal agent of Sawyer or JP7277975 would render the claimed subject matters of claims 1 and 18 obvious. Applicants respectively disagree with this assertion as set forth below.

None of the cited references teach a "water-soluble plasticizer" as claimed. However, the Examiner asserted that Sawyer teaches oxyethylene oxypropylene copolymer as a plasticizer. The oxyethylene oxypropylene copolymer of Sawyer cited by the Examiner is poly (oxyethylene-oxypropylene) glycol *bis* (4-aminobenzoate). See the third paragraph in page 5 of the Office Action and column 13, line 39 of Sawyer. A solubility of this copolymer of Sawyer in water is low because the hydroxyl groups at both ends of the copolymer are protected with aminobenzoate which is hydrophobic. Therefore, this copolymer is not a water-soluble plasticizer as required by claims 1 and 18 which recite "a water-soluble plasticizer in a form of a

solid or a paste at 20°C at 1 atm". This is further evidenced in that the composition of Sawyer forms a solid film when applied to the nail. *See* at column 25, lines 42 to 54; column 26, lines 1 to 2 of Sawyer. On the contrary, the claimed composition of the present application forms a viscous glass state film allowing components to move inside the film. *See*, for example, paragraph [0063] of the published application.

JP7277975 teaches treatment of external skin conditions. This reference, however, does not teach some features of the independent claims 1 and 18. For example, as correctly mentioned by the Examiner, it does not disclose the specific antifungal agents and the specific plasticizers of the claims. *See* at page 5, lines 1-2 of the Office Action. Furthermore, JP7277975 also fails to teach a water-soluble plasticizer as per claims 1 and 18 because, when applied to the skin, the composition of JP7277975 forms a solid film, not a coating film having a viscous glass state as per the invention. *See* paragraphs [0007] and [0009] of JP7277975. Therefore, JP7277975 alone or even in combination with Kodama fails to teach the subject matters according to claims 1 and 18.

The feature that the antifungal composition forms a coating film when applied to an application target is a result of the structural characteristics including the inclusion of a plasticizer which is water-soluble. This feature has been incorporated to claims 1 and 18. Support is found in canceled claims 13-14.

As noted, the combination of JP7277975 and Kodama or Sawyer and Kodama still fails to disclose every element of claims 1 and 18. Furthermore, even the combination of all three references still fails to disclose the subject matters of the claims. Therefore, no *prima facie* case of obviousness is established to claims 1 and 18 over the references. Applicants respectively request withdrawal of the rejection to the independent claims.

As to claims 4, 6, 8-12, 15-17, and 19, they incorporate all the limitations of claim 1 through their dependency from claim 1. As noted, the cited references alone or in combination fail to teach at least some elements of claims 4, 6, 8-12, 15-17, and 19. Therefore, these dependent claims are patentable over the references for at least the same reasons that claim 1 is patentable in addition to their own patentable features. Applicants respectively request withdrawal of the rejections and reconsideration of the claims.

Application No.: 10/518,776
Filing Date: December 17, 2004

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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